DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

JUN 23 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-13

Anthony Paytas, Chairman/CEO
Genesis Laboratory, Inc.
28177 Palomino
Warren, Michigan 48093

Dear Sir:

This letter is in reference to the promotion, marketing, and distribution of the product "HMC-1023".

The promotional literature for the product makes extensive claims for the treatment and cure of cancer. Examples of claims for the product include [emphasis with capital letters is found in the firm's promotional materials]:

From "History of HMC-1023":

- "... it cured me of my terminal condition in an astounding five and one half weeks and it has demonstrated other significant activities as well ... I've also had a CEA (Carcino Embryonic Antigen) blood test which determines if any cancer cells are in the bloodstream. This test also came back negative... A recent Cystoscopy showed all previous bladder cancer tumors were gone ...";
- "Also a 66 year old female with Chronic Lymphocytic Leukemia with an elevated white blood count, who has been on HMC-1023 for 30 days. She returned to her doctor for an updated CBC ... amazed in the drop at her white cell count"
- "Another subject ... with "end stage" lung cancer ... has been on HMC-1023 for nine weeks ... it was discovered that NO TRACE OF THE LUNG CANCER WAS ABLE TO BE FOUND.";

- "Two other subjects ... with advanced skin cancer ... with HMC-1023, an extract of HMC-1023 was used topically. Within two weeks all traces of both subjects tumors was gone ...";

From "Documents You Must Produce":

- "During my research it was determined that SIGNIFICANT tumor reduction and/or elimination was accomplished by many of the herbs ultimately used in HMC-1023. Other herbs showed great power in keeping tumors and cancer cells from spreading.";

From "Genesis Laboratory Disclaimer":

- "Most of the ingredients in this product, Genesis HMC-1023, have been shown or suspected, by independent research or historical use, to have a detrimental effect on CANCER cells or TUMORS ...";

- "... as an effective TREATMENT OR CURE FOR BLADDER CANCER AND POSSIBLY OTHER TYPES OF CANCER AS WELL";

Based on the claims made for the product and its intended use, the product is a drug [Section 201(g) of the Food, Drug, and Cosmetics Act (the Act)]. It is also a new drug [Section 201(p) of the Act] and may not be legally marketed in the United States without an approved New Drug Application (§505).

This drug is misbranded [§ 502(f)(1)] because the labeling fails to bear adequate directions for use and because the labeling is false and misleading as it suggests that the product is safe and effective for its intended use when this has not been established [502(a)].

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Mrs. Judith A. Putz, Compliance Officer; U.S. Food and Drug Administration; 1560 East Jefferson Avenue; Detroit, MI 48207 (telephone: 313-226-6260, ext. 137).

Sincerely,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District